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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,052	02/20/2004	Anthony Cerami	CC98-002B04-US	6770
7590 Frederick J. Hamble 712 Kitchawan Rd. Ossining, NY 10562				
EXAMINER				
HOLT, ANDRIAE M				
ART UNIT		PAPER NUMBER		
1616				
MAIL DATE		DELIVERY MODE		
05/15/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary****Application No.**

10/783,052

**Applicant(s)**

CERAMI ET AL.

**Examiner**

Andriae M. Holt

**Art Unit**

1616

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 76 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 76 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

### **DETAILED ACTION**

The Examiner of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Andriae M. Holt.

Claim 76 is pending in the application. Claim 76 has been amended.

Applicant's arguments with respect to claim 76 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 102***

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 76 is rejected under 35 U.S.C. 102(a) as being anticipated by Emery et al. (5,538,733).

Emery et al. disclose a method of priming an immune response in a 1-90 day old animal, in the presence of circulating maternal antibodies by employing a biocompatible implant containing an immunogenic agent (antigen, instant invention) (col.3, lines 57-60). Emery et al. disclose the implants administered according to the method are those known in the art that comprise a biocompatible, non-toxic material. Emery et al. disclose the implants useful in the method have a matrix structure that will allow for incorporation of the immunogenic agent and release of the agent at a desired rate (col. 4, lines 19-24) (limiting the passive diffusion of antigen or an immune cell secretory product without limiting the active movement of immune cells, instant invention). Emery et al. disclose the preferred implant is made of a biocompatible solid phase polymeric matrix (porous

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matrix that contains the antigen) that is bioabsorbable, biodegradable, and/or bioerodible in the body of the animal and will deliver an immunogen into tissue fluids over an extended period without irritation and adverse effects to the animal (col. 4, lines 25-29). Emery et al. disclose the implant is administered to the animal at about 1-90 days of age (implanting into the body, instant invention). Emery et al. meet all the limitations of the claim.

Claim 76 is rejected under 35 U.S.C. 102(a) as being anticipated by Barr et al. (5,593, 697).

Barr et al. disclose a pharmaceutical implant, which when parenterally administered releases a pulse of at least one biologically active material, at a controlled time interval after implantation. Barr et al. disclose the implant comprises a) a biologically active material, which can be an antigen, (antigen, instant invention); b) an excipient comprising at least one water soluble material and at least one water insoluble material, (porous matrix, instant invention) c) a polymer film coating adapted to rupture at a predetermined period of time after implantation (container that has a means for limiting passive diffusion, instant invention). Barr et al. disclose the function of the water insoluble materials is to provide a physical form to the implants which does not break up when it hydrates (col. 3, lines 55-57). Barr et al. disclose the polymer films are applied to the compressed cores using standard film coating procedures and it includes a bilayer coating comprising an insoluble biocompatible film and an enteric polymer and a single film comprising a mixture of insoluble and biodegradable polymers (col. 4, lines 15-22). Barr et al. further discloses a method of administration of a biologically active

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material to a mammal, comprising the step of implantation of an implant (immunizing by implanting, instant invention). Barr et al. meet all the limitations of the claims.

None of the claims are allowed.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andriae M. Holt whose telephone number is (571)272-9328. The examiner can normally be reached on 7:00 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richter Johann can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Andriae M. Holt  
Patent Examiner  
Art Unit 1616

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/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616